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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/005,753

10/29/2001

Yasuhiro Sakai

3029-74

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7590

07/27/2004

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,753

Applicant(s)

SAKAI ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-16-04, 2-9-04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 17, 2004, has been entered.

The amendment filed May 17, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 20-27 and 29 are pending.

Election/Restrictions

Applicant's election of the species wherein the nitrite reducer is sulfamic acid, in Paper No. 5, filed June 9, 2003, is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Because a composition comprising a polymethine dye, sulfamic acid as a nitrite reducer (the elected species) and a buffer for maintaining an acidic pH

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is considered free of the prior art, examination has been extended to other species within the Markush group of claim 21.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Jackson (U.S. Pat. 5,668,011).

Jackson '011 describes a test kit for determining the presence of *Helicobacter pylori* using urease as a marker enzyme. The described kit contains bromophenol blue dye, which can stain bacteria, Tris buffer and sulfamic acid, the elected species of nitrite reducing substance. See column 2, lines 18-32. Thus, Jackson '011 discloses a composition comprising all of the claimed ingredients, including the elected species of nitrite reducing reagent.

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Claims 20-27 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Inoue et al (EP 1 136 563 A2).

Inoue discloses processes whereby a reagent comprising a polymethine dye and a quaternary ammonium surfactant, at a pH ranging from 2.0 to 3.0, buffered by a compound having a pKa of 1 to 5.5., is used to stain bacteria. See pages 3-7, describing the suitable dyes and surfactants. One of the suitable buffers is explicitly stated to be glycine. See paragraph [0026] on page 7. Thus, glycine may function as both the buffer recited in the claims under examination, and the nitrite reducing agent. In sum, by describing a composition containing the claimed dyes, the claimed surfactants, and glycine, Inoue describes the claimed composition. A holding of anticipation is therefore required.

It is noted that the September 26, 2001, publication date of the Inoue patent is after applicant's foreign priority date of November 1, 2000. However, applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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Claim Rejections - 35 USC § 103

Claims 20-24, 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizukami et al (EP 0 882 983 A2) in view of Kohnert et al (U.S. Pat. 5,366,730).

Mizukami discloses processes whereby a reagent comprising a polymethine dye and a quaternary ammonium surfactant, at a pH ranging from 4.5 to 11, is used to differentially stain leukocytes. See pages 3 and 4. Mizukami differs from the claims failing to disclose the inclusion in the reagent of a substance capable of reducing nitrite ions.

However, Mizukami clearly discloses the desirability of using a buffer in the composition. See, e.g., page 3, lines 42-44. One of ordinary skill in the art clearly would have recognized that ascorbic acid was suitable for use as a buffer within the pH range (4.5 to 11) described by Mizukami as being useful for the staining reagent disclosed therein. For example, Kohnert, in Table 1 at column 3 discloses an ascorbic acid/NaOH buffer for maintaining t-PA at pH 6.0. Recognizing the suitability of ascorbic acid as a buffer in Mizukami's staining reagent, the artisan of ordinary skill would have been motivated to have included it in Mizukami's staining reagent. Thus, the artisan of ordinary skill would have been motivated to have included a compound which meets the claim limitations of being

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both a buffer for maintaining an acidic pH, and being a nitrite ion reducer. A holding of obviousness over the cited claims is therefore required.

Response to Arguments

All of applicant's argument has been fully considered but is not persuasive of error. With respect to the rejection over Jackson, applicant is simply incorrect in asserting that the Tris buffer of Jackson, if used to maintain an acidic pH, would render inoperable the reagent described therein. The reaction measured by the Tris-containing reagent disclosed by Jackson is the color change of bromophenol blue, which occurs at an acidic pH. Thus, the Tris buffer used in the reagent described by Jackson necessarily maintains an acidic pH. Otherwise the bromophenol blue color change could not be measured.

With respect to the remaining claims, note specifically that claim 20 cannot be considered allowable because, contrary to their argument, applicant has not amended that claim to recite a composition containing the combination of ingredients considered to be allowable. Rather, as evidenced by the rejections set forth above, claim 20 and its dependents are still sufficiently broad so as to encompass compositions suggested by the prior art.

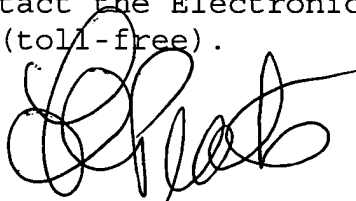
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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Francisco C Prats', is positioned above the printed name and title.

Francisco C Prats
Primary Examiner
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FCP